The Office of the National Coordinator for Health Information Technology

# Direct – Laboratory Reporting Workgroup

# Presentation to CLIAC

August 29, 2012

# Why was this workgroup formed?

- States had plans to utilize Direct for reporting of laboratory results to meet Stage 1 Meaningful Use requirements, especially for underserved communities
- The laboratory industry was not moving to adopt Direct for reporting laboratory results (in particular, the “report of record”)
- Concerns were expressed regarding the impact of Direct on laboratory accreditation
- Specific issues had been raised about:
  - CLIA regulations and guidance
  - Reliability of Direct for laboratory reporting
  - Operational issues related to Direct
  - Security of Direct

# Why was CLIA an issue

- Sec. 493.1291 Standard: Test report
  - The laboratory must have adequate manual or electronic systems in place to **ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner.**
  - **Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results** and the laboratory that initially requested the test.

- Sec. 493.1299 Standard: Postanalytic systems assessment
  - The laboratory must establish and follow written policies and procedures for an **ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in Sec. 493.1291.**

# Workgroup Charge

1. Identify any regulatory and operational issues with Direct Project messaging that prevent or limit adoption by clinical laboratories for transmitting the “Report of Record” to the Final Report Destination
2. Identify mitigation strategies for each of the issues
3. For regulatory issues, work with ONC and CMS/CLIA to ensure that, where appropriate, guidance is issued to CLIA accrediting agencies to enable the use of Direct messaging for lab reporting

# What is the Direct Project?

A project to create the set of **standards** and **services** that, with a **policy** framework, enable simple, directed, routed, scalable transport over the Internet to be used for secure and meaningful exchange between known participants in support of **meaningful use.**


**http://directproject.org**

# Direct: An alternative to legacy mechanisms

**When current methods of health information exchange are inadequate:**

**Communication of health information among providers and patients still mainly relies on mail or fax**

- Slow, inconvenient, expensive
- Health information and history is lost or hard to find in paper charts

**Current forms of electronic communication may not be secure**

- Encryption features of off-the-shelf e-mail clients not often used in healthcare communications today

**Physicians need to transport and share clinical content electronically in order to satisfy Meaningful Use requirements**

- Need to meet physicians where they are now

# Direct: Facilitates Meaningful Use

**Direct facilitates the communication of many different kinds of content necessary to fulfill meaningful use requirements.**

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DIRECT

**Examples of Meaningful Use Content**

- **Patients:**
  - Health information
  - Discharge instructions
  - Clinical summaries
  - Reminders
- **Public Health:**
  - Immunization registries
  - Syndromic surveillance
  - Laboratory Reporting
- **Other Providers/Authorized Entities:**
  - Clinical information
  - Labs – test results
  - Referrals – summary of care record

# Direct: Who is using it?

**EHRs**

- Amazing Charts
- ApeniMED
- Allscripts
- Quest Diagnostics Care 360
- Cerner Corporation
- eClinicalWorks
- e-MDs
- Epic
- GE Healthcare
- Greenway
- NextGen
- Polaris
- Siemens
- SOAPware

**States**

| | | |
|---|---|---|
| Alabama | Louisiana | Oregon |
| Alaska | Maine | Pennsylvania |
| American Samoa | Massachusetts | Puerto Rico |
| Arizona | Minnesota | Rhode Island |
| Arkansas | Mississippi | South Carolina |
| California | Missouri | South Dakota |
| Colorado | Montana | Tennessee |
| Connecticut | Nebraska | Texas |
| Delaware | Nevada | Utah |
| District of Columbia | New Hampshire | Vermont |
| Florida | New Jersey | Virgin Islands |
| Georgia | New Mexico | Virginia |
| Guam | New York | West Virginia |
| Hawaii | North Carolina | Wisconsin |
| Idaho | North Dakota | Wyoming |
| Kansas | Ohio | |
| Kentucky | Oklahoma | |

**HIEs / HISPs**

- Ability
- Axolotl
- Harris
- Health-ISP
- Inpriva
- Kryptiq Corporation
- Max.MD
- Medicity
- Mirth
- Secure Exchange Solutions
- Surescripts

**PHRs**

- Microsoft
- Nomoreclipboard.com
- SmartPHR

**The above are examples of vendors (EHRs, PHRs, HIEs/HIPSs) and states that have incorporated or are planning on incorporating the Direct Project protocol into their products/ strategies. Plans may have changed in the interim as of 10/2011.**

# Direct Addresses

- Direct Addresses are used to route information
  - Look like email addresses
  - Used only for health information exchange


- An individual may have multiple Direct addresses

# Direct Messages

- Direct Messages are secure email messages
  - RFC 5322
  - Headers
  - Contents – text plus attachments
  - Security information – signatures, certificate information as applicable
- Contents can be structured or unstructured
  - Text and other human-readable representations
  - CCD, CCR
  - PDF, TIFF
  - HL7 lab results
  - IHE XDM specifications

# Message Transport & Delivery

- Direct uses Simple Mail Transport Protocol (SMTP) as its primary mechanism for delivering healthcare content from a sender to a receiver
  - Widely supported and very scalable
- Direct uses S/MIME to encrypt the message content while “on the wire.”
  - X.509 digital certificates (PKI) used to sign/encrypt
  - “Security Agent” runs at the HISP (“Health Information Service Provider”)

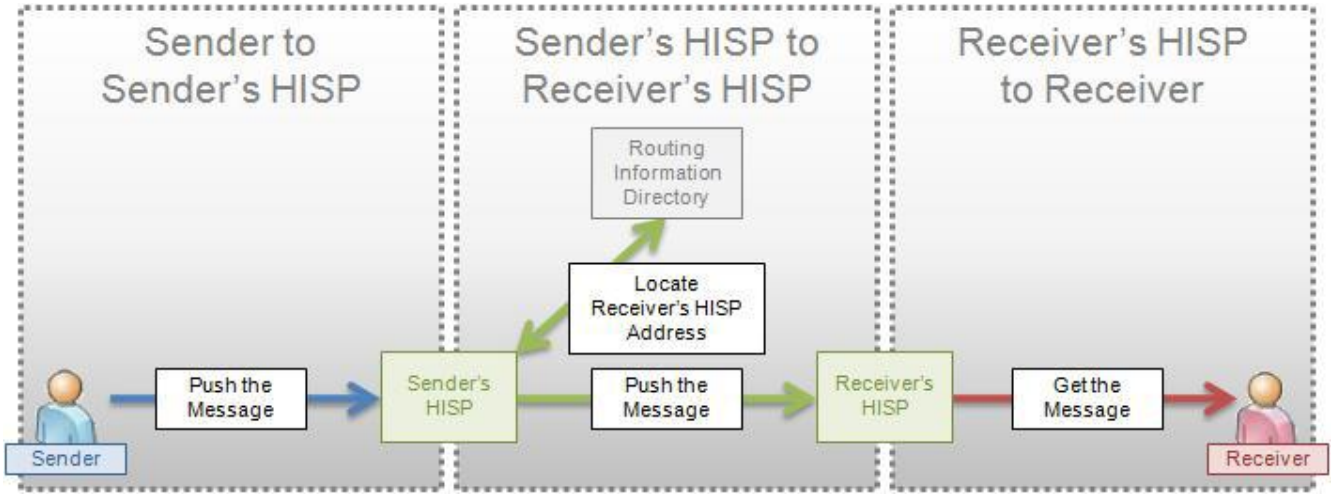
# Direct & Digital Certificates

- Each Direct Address **must** have at least one digital certificate associated with it in order to securely transmit and receive health information
- By using certificates to securely transmit and receive information…
  - The Sender has a strong mathematical certainty that only the Receiver or explicitly authorized delegates can view the message
  - The Receiver has a strong mathematical certainty that only the Sender sent the message
  - Both Sender and Receiver have confidence that nothing happened to the message in transit (e.g., tampering, disclosure, etc.)

# What is a Health Information Service Provider (HISP)?

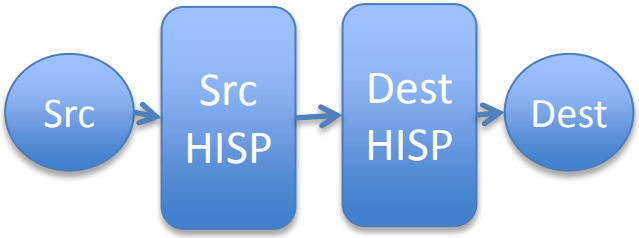
A HISP is in charge of performing a number of services required for the exchange of health information as defined by the Direct Project. These services may be handled by a third party or by the sender/receiver.

- Provide Direct Addresses
- Publish/manage digital certificates
- Encrypt and route Direct messages
- Depending on implementation model (e.g., web portal), possibly store Direct messages



# Deployment Models


- **Encryption at Client**
  - Client does encryption/decryption locally
  - Capabilities built into EHRs and Email Clients
  - Relies on HISP for routing

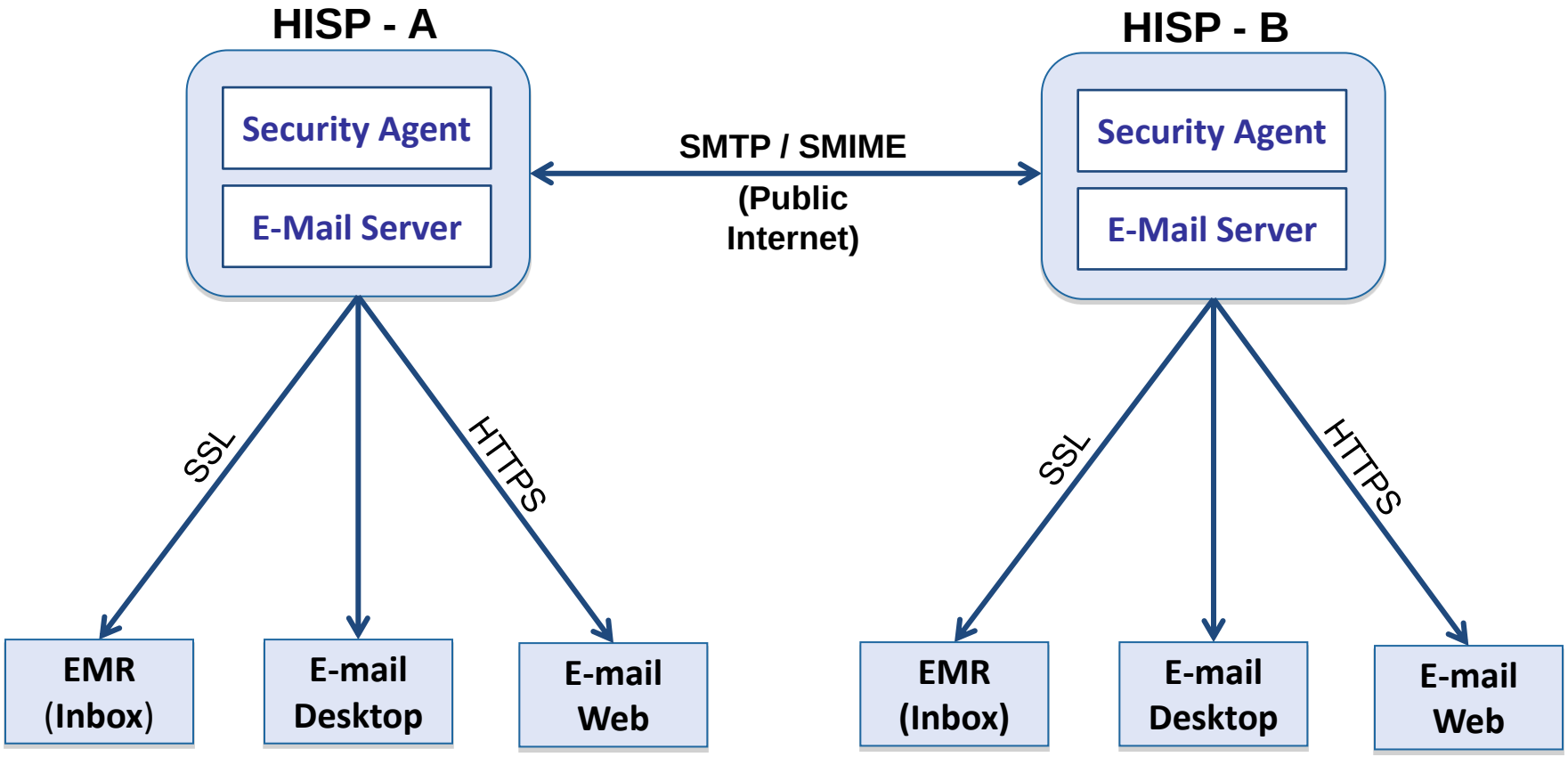



- **Encryption at HISPs**
  - HISP provides encryption/decryption
  - HISP provides routing
  - Client interacts through EHR, Email Client, or Portal

Individual communities likely to employ all deployment models, depending on provider preferences and local EHR choices.

# How Does Direct Work? Bringing the Pieces Together

HISP = "Health Information Service Provider"



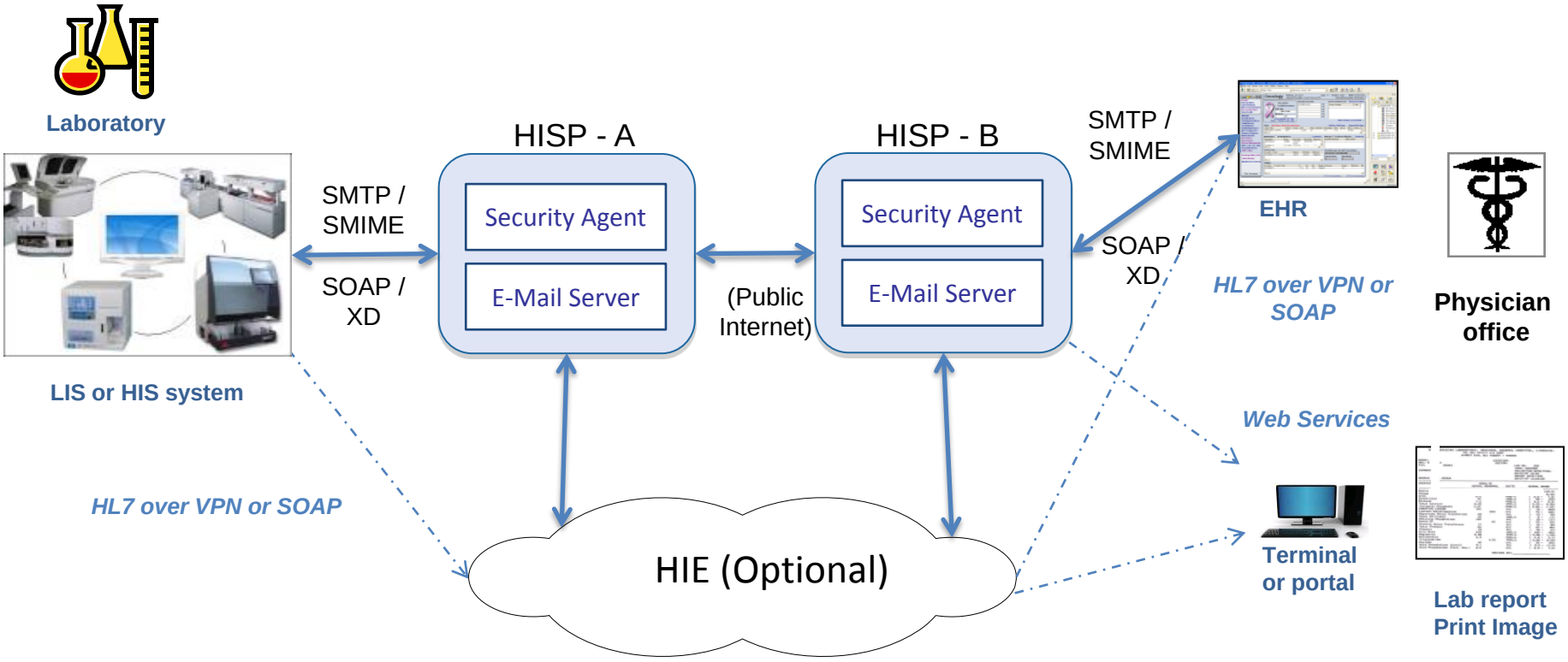
# Current Lab Workflow

- Order Options
  - Communicated via “paper” requisition or via electronic methods supported by laboratory (see methods below)
- Test performed, QA reviewed, result(s) released
- Delivery “Report of Record” to Final Report Destination
  - Printed report via US Mail or Courier
  - Report image via FAX or “remote” printer in physician office
  - Electronic report data via agreed upon “standard” (e.g. HL7 2.x.x) over VPN and MLLP or SOAP service

# Electronic Laboratory Results Reporting via Direct

Multiple paths are possible depending on the specific implementation of Direct

Direct will require predictable positive acknowledgement of delivery success or failure to meet CLIA accreditation and operational needs of laboratories



# Direct Implementation Guide for Destination Delivery Notification

- Guide details how to implement timely, predictable acknowledgement of positive or negative delivery within a Direct context
- Requires HISPs to indicate successful or failed delivery to destinations, what constitutes delivery "success" or "failed" notifications
- Responsibilities of the Sending and Receiving HISPs around these notifications

# Destination Delivery Notification Technical Details

- Need for destination delivery notifications is indicated within the Message Disposition Notification (MDN) request in the headers of the sent message
- Positive destination delivery notification (e.g., “success”)
- Negative destination delivery notification (e.g. “failure”)

# Summary of Workgroup Effort

Problem

- Direct dose not have a standard method to notify a sender of the success or failure of to deliver a message

CLIA implications

- CLIA requires that test reports must be sent to the authorized person in an accurate, reliable, confidential and timely manner.
- Direct does not guarantee reliable or timely delivery

Solution

- Creation of the “Implementation Guide for Delivery Notification in Direct” that defines the requirements for a delivery notification process based on standard messages that can be implemented within the Direct messaging framework.
- Direct implementations supporting this guide meet the CLIA requirements for reliable and timely delivery.

Status of Solution

- The Direct reference implementations have been updated to include the requirements from the new delivery notification guide and are generally available.

Conclusion

- Direct messaging that incorporates the new delivery notification requirements is an acceptable and secure transport for laboratory result reporting.

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# Laboratory Reporting Workgroup (Tiger Team)

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# Workgroup Charge

Background

Historically, the variability in interface standards, clinical vocabulary, and Electronic Health Record system (EHR) technology coupled with the lack of EHR standardization, testing and certification required verification of test result presentation (e.g. "visual verification") for each implementation of an EHR, the only practical method for laboratories to ensure patient safety and laboratory best practice. This practice, as implemented, presents a significant barrier in terms of cost and implementation time to establishing electronic interfaces between clinical laboratories and EHRs.

Discovery Phase

Review the current status of interface standards, clinical vocabulary, testing methodologies and certification processes with regard to EHRs and ambulatory laboratory testing at a level of detail that will allow the development of a proposed timeframe and scope of effort for the Action Phase

Action Phase

Provide specific actionable steps regarding standards, testing, certification and policy that, when implemented, will minimize the time, cost and operational impact of establishing new EHR to laboratory interfaces in the ambulatory care environment while maintaining or improving the quality of the presentation of laboratory results to the Authorized Person.

# Workgroup Participants

Current Participants

- Association of Pathology Informatics (API)
- College of American Pathologists (CAP)
- Centers for Medicare and Medicaid Services (CMS)
  - Division of Laboratory Services
- Centers for Disease Control and Prevention (CDC)
  - Laboratory Practice Standards Branch
- LabCorp
- Methodist Hospital of Omaha
- Office of the National Coordinator (ONC)
- Quest Diagnostics

Additional Organizations

- EHR / LIS Vendors (3-4 TBD)

# CLIA Guidance (S&C-10-12-CLIA)

Issued March 1, 2010 – FAQ section – Number 6

If all interfaces or electronic communication software used between a laboratory and an EHR system are identical, is verification of accuracy of test result transmission required at all sites which use this interface? If a laboratory has multiple sites interfaced to an EHR/HIE that utilize different interface software, do they all need to be checked?

- CLIA does not prescribe the means by which a laboratory would test the accuracy and timeliness of their test report transmissions. Laboratories utilize varying test methods/devices for this testing, including manual and automated methodologies/devices.
- Each laboratory, its test systems, and processes are unique; therefore, laboratories must devise their own methods to check for the accurate and timely transmission of test results. This may include identifying means of checking the accuracy and timeliness of intermediate systems through which test results travel to reach the authorized person or their designated agent.
- Further, extensive laboratory oversight experience has demonstrated that devices do not always work properly in the field. This necessitates the testing of every interface to ensure that that interface is operating as it should. The protocol, method, and frequency for verifying the accuracy of an electronic test result transmission through an interface to an EHR/HIE to the authorized person are determined by the laboratory. Again, we would not anticipate the need for visual inspection of each interface/terminal within an EHR installation.

# Current Verification Process (typical)

For each provider's EHR

1. Laboratory and provider's EHR vendor agree on standard transaction requirements
2. Establish physical connectivity and lower level transport
3. Verify basic exchange of test information
4. Laboratory sends test messages with a range of tests and result types
5. Provider generates a screen print for each "test report" and send the screen prints to the laboratory
6. Laboratory verifies accuracy, completeness, usability of test information (including any translations) as well as the availability of all CLIA required information
7. Gaps are identified and reported to the provider for correction
8. Steps 4-7 are repeated until all "test messages" are displayed in an acceptable manner

Conclusion:

Expensive and time consuming process that tests a limited subset of all test reports for an individual provider at one point in time.

# Definitions

**Laboratory Test Results –** result of laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health.

**Covered Environment –** electronic laboratory test results reporting between a Laboratory Information System (LIS) and the Electronic Health Record system (EHR) of an ambulatory care provider in the US.

# Workgroup Goals

Overall

Reduce the time and cost to implement and verify (e.g. visual verification) laboratory result reporting interfaces, in the ambulatory environment, while maintaining the accuracy, completeness and usability of laboratory test result information viewed by the authorized person for safe and effective interpretation.

Discovery Phase

Develop subject areas, level of effort and timeline

Execution Phase

Provide recommendations regarding the following subject areas to achieve the overall goal

- Standards
  - Use of and changes to Implementation Guides for Laboratory Reporting Interface (LRI), Laboratory Orders Interface (LOI) and electronic Directory of Services (eDOS)
  - Use of standard clinical vocabulary for laboratory testing
- Testing and Certification
  - NIST validation suite use cases and data sets
  - NIST usability framework
  - EHR certification requirements
- Policy
  - Guidance from CMS regarding CLIA
  - FDA guidance regarding laboratory testing and transfusion software
  - Accreditation Agencies' relevant policies
  - CMS's Conditions of Participation in regard to authentication of interpretative reports
  - ONC requirements for EHR certification and CMS requirements for meaningful use

# Out-of-Scope

- Secondary use of laboratory data (i.e., public health or bio surveillance uses of the reported laboratory results).
- Ordering and reporting of laboratory results in the acute care setting.
- Results not transmitted via structured electronic transactions (explicitly: mail, remote printing and fax) – laboratories should follow current accepted verification procedures for these laboratory reporting methods

# Discovery Effort Sequence and Timeline

- Establish Discovery workgroup
- Develop and agree on goals, scope, assumptions
- Determine specific in-scope subject areas that need elaboration

3-4 weeks

- Develop in-scope subject areas
  - Involve subject matter experts where appropriate
  - Define level of effort to explore/resolve each subject area
  - Create timeline for each subject area
- Develop overall timeline and level of effort
- Review with ONC and CMS

8-12 weeks

- Decision to proceed

2-3 weeks